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FEATURED ARTICLE

Implementation of a Symptom-Triggered Benzodiazepine Protocol for Alcohol Withdrawal in Family Medicine Inpatients

Sharon See, PharmD, BCPS, Sarah Nosal, MD†, Wendy Brooks Barr, MD, MPH, MSCE‡, Robert Schiller, MD§*

Abstract

Purpose: The purpose of this pilot study was to review the implementation of symptom-triggered benzodiazepine therapy and evaluate the feasibility and outcomes as compared with a previous hospital standard of fixed-dose phenobarbital protocol for alcohol withdrawal on a family medicine service.

Methods: This retrospective chart review of 46 patients' medical records was performed on admissions to the family medicine service occurring between February and October of 2005 compared with February and October of 2006. Included in the study were adults who were suffering from alcohol withdrawal symptoms (AWS), who admitted to heavy daily alcohol intake, who were intoxicated on admission, and who had a history of AWS and/or history of AWS-related seizures. The Clinical Institute Withdrawal Assessment for Alcohol Scale, Revised (CIWA-Ar) was used to evaluate the impact of individualized symptom-triggered therapy on outcome measurements utilizing symptom-triggered benzodiazepine therapy compared with the previous hospital standard using a fixed-dose phenobarbital protocol.

Results: One hundred percent of the patients in the phenobarbital group required drug compared with 38% in the benzodiazepine group ($P < 0.001$). Fewer patients (9.5%) in the benzodiazepine group left the hospital against medical advice (AMA), while 36% of patients in the phenobarbital group left AMA ($P = 0.045$). There was no significant difference in length of stay or the number of days on the protocol.

Conclusion: The results of the pilot study demonstrated that symptom-triggered therapy using benzodiazepines resulted in better outcomes than fixed-dosing phenobarbital. Importantly, most patients in the benzodiazepine group required no drug administration.

Key Words—alcohol withdrawal, benzodiazepines, symptom-triggered therapy

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INTRODUCTION

Alcohol dependence is a major health problem in the United States, affecting approximately 8 million Americans.[1] Alcohol withdrawal syndrome (AWS) is defined as the discontinuation or reduction of prolonged, heavy alcohol use that results in the development of minor or major withdrawal symptoms. Minor withdrawal symptoms, including tremor, hypertension, diaphoresis, and tachycardia, occur in about 6 to 12 hours, often while the patient still has a measurable blood alcohol level. The most significant complications of alcohol withdrawal, seizures and delirium tremens, typically occur within 48 to 96 hours from the last drink.[2] Although AWS in the general US population is rare and usually mild, symptoms of alcohol withdrawal relate proportionately to

*Associate Clinical Professor, St. John's University College of Pharmacy and Allied Health Professions, Jamaica, NY; Clinical Faculty, The Institute for Family Health, New York, NY; †Family Physician, Urban Horizons Family Practice, Bronx, NY; ‡Research Director, The Institute for Family Health, New York, NY; Assistant Professor of Family and Social Medicine, Albert Einstein College of Medicine, Yeshiva University, Bronx, NY; §Chair, Alfred and Gail Engelberg Department of Family Medicine, The Institute for Family Health; Senior Vice President Medical Affairs, Institute for Urban Health, Albert Einstein College of Medicine, Yeshiva University Bronx, NY. Corresponding author: Sharon See, PharmD, BCPS, St. John's University College of Pharmacy and Allied Health Professions, 8000 Utopia Parkway, Jamaica, NY 11439; phone: 212-844-1955; e-mail: sees@stjohns.edu.

the amount of alcohol intake and the duration of a patient's recent drinking habit. According to a recent analysis, patients who consume more alcohol (more than 10 drinks/week) are more likely to report withdrawal symptoms.[3] To avoid the lethal stages of AWS, clinicians must be vigilant during this critical 6- to 96-hour window.

The American Society of Addiction Medicine lists 3 goals for detoxification of alcohol and other substances: "to provide a safe withdrawal from the drug(s) of dependence and enable the patient to become drug-free," "to provide a withdrawal that is humane and thus protects the patient's dignity," and "to prepare the patient for ongoing treatment of his or her dependence on alcohol or other drugs."[4]

To accomplish these goals, several agents have been administered to patients to manage the manifestations of AWS. These agents include barbiturates, benzodiazepines, beta-adrenergic blockers, carbamazepine, clonidine, magnesium, and neuroleptic agents. The ideal agent should be cross-tolerant with alcohol. It should have sedative, anxiolytic, and anticonvulsant activity; a rapid onset and long duration of action; a wide margin of safety; metabolism independent of liver function; and a low potential for abuse.[5]

Benzodiazepines are the standard of care for the pharmacologic management of alcohol withdrawal. Benzodiazepines have been shown to be superior to placebo in treating alcohol withdrawal symptoms as well as seizures and delirium.[6] A meta-analysis showed that, compared with placebo, benzodiazepines reduced withdrawal severity, incidence of delirium (P = 0.04), and seizures (P = 0.003).[7] The most commonly used benzodiazepines for the treatment of AWS are diazepam (*Valium*), chlordiazepoxide (*Librium*), and lorazepam (*Ativan*). Diazepam, a longer-acting agent, has a rapid onset, can be easily titrated with loading doses, and provides a smooth withdrawal due to its long half-life (48 to 72 hours) and active metabolite (desmethyldiazepam) but has the potential to cause excess sedation in elderly patients or patients with hepatic dysfunction due to impaired clearance. Similarly, chlordiazepoxide is also long acting, has active metabolites (desmethylchlordiazepoxide and demoxepam), and may cause oversedation in elderly patients or patients with hepatic dysfunction. Its onset, however, is slower than diazepam.[8] Lorazepam may be a better pharmacologic choice for these patients because it does not have active metabolites and undergoes oxidation. However, oversedation during the loading phase with lorazepam may occur because peak sedation may not occur for 10 to 20 minutes compared to minutes with diazepam.

Adrenergic agents such as beta-blockers and clonidine are sometimes used to control the autonomic symptoms of alcohol withdrawal, such as elevated blood pressure. They are generally not recommended as sole treatment for alcohol withdrawal because they do not treat the underlying mechanisms of alcohol withdrawal and may mask signs of delirium or other markers of withdrawal.[2,7] Carbamazepine has been shown to be effective for alcohol withdrawal symptoms. When compared with benzodiazepines, carbamazepine has been shown to be equally effective for alcohol withdrawal and to be helpful with secondary outcomes such as anxiety and depression. Carbamazepine offers an advantage over benzodiazepines in that it does not provide additive CNS suppression when taken with alcohol and has an established record as an antiepileptic drug.[2,8] Routine magnesium replacement is not recommended because it has not been shown to have any effect on severity of alcohol withdrawal symptoms, seizures, or delirium.[9]

Although there is a lack of well-designed, prospective trials demonstrating the efficacy of phenobarbital for AWS, our institution continues to use it as a primary therapeutic agent.[7] The rationale for the use of phenobarbital is that it is cross-tolerant with alcohol; has a long duration of action; can be administered orally, intramuscularly (IM), and intravenously (IV); is relatively inexpensive; and has a low potential for abuse. Despite these advantageous characteristics, phenobarbital has a less desirable safety profile than benzodiazepines. It may produce oversedation, hypotension, and respiratory depression, and lacks clinical data from controlled, comparative trials to support its use as a primary agent for alcohol withdrawal. Furthermore, hepatic enzyme induction occurs with extended phenobarbital use and may create the potential for multiple drug interactions.[5]

Controversy exists over the best dosing regimen for patients suffering from AWS. Patients are either given regular "around the clock" doses of agents, also known as the "fixed-dose" regimen or patients are individually assessed with the Clinical Institute Withdrawal Assessment for Alcohol Scale, Revised (CIWA-Ar) tool and given doses based on an elevated objective score, also known as the symptom-triggered approach. The CIWA-Ar is a validated 10-item scale that assesses the severity of alcohol withdrawal and aids in monitoring response to treatment (see Appen-

dix A).[10] Unlike fixed-dose regimens, symptom triggered therapy allows for drug administration when needed by the patients, as opposed to administering drug when there may be no need or benefit.[7] The main advantage to the symptom-triggered approach is that much less medication is used to achieve the same withdrawal state. Daeppen et al[11] performed a prospective, double-blind, randomized, controlled-treatment trial to study the benefits of an individualized treatment regimen on the quantity of benzodiazepines administered and the duration of its use during alcohol withdrawal treatment.[11] The authors compared oxazepam given either on a fixed dose or as a symptom-triggered schedule using the CIWA-Ar assessment tool. The symptom-triggered oxazepam patients required less drug (37.5 ± 81.7 mg) and were on the protocol for less time (20 ± 24.45 hours) than the fixed-dose group (231 ± 29.43 mg and 62.7 ± 5.44 hours, respectively).

Based on the evidence in the literature, the continued use of fixed-dose prescribing with phenobarbital needed to be evaluated and possibly replaced with the CIWA-Ar tool using benzodiazepines. The goal of this study was to investigate the introduction of this symptom-based treatment protocol in a limited inpatient setting operated by the family medicine department.

METHODS

This was a retrospective study of hospitalized patients admitted to the family medicine unit who were older than 18 years of age and suffering from AWS, admitted to heavy daily alcohol intake, were intoxicated at admission, and had a history of AWS and/or history of AWS-related seizures. Patients who had a contraindication to benzodiazepines or hypersensitivity to benzodiazepines were excluded from the study. The objective of the study was to evaluate newly implemented symptom-triggered therapy using the CIWA-Ar scale, evaluate the impact of individualized symptom-triggered therapy on outcome measurements, and compare symptom-triggered benzodiazepine therapy to a previous hospital standard using phenobarbital in a fixed-dose protocol.[10] A retrospective chart review of patients receiving the symptom-triggered benzodiazepine protocol during the period of February to October 2006 was compared with patients who were treated with fixed-dose phenobarbital during the period of February to October 2005. The outcome measurements included quantity of medication used, duration of drug treatment, inpatient length of stay, number and type of withdrawal-related complications experienced, and adverse effects experienced. Adverse events were determined by a retrospective chart review. Our protocol used oral diazepam or lorazepam, and IM lorazepam if the patient could not tolerate anything by mouth (see Appendix B). Hospital policy did not allow for IV administration of benzodiazepines on the general medical floor. Nurses assessed each patient using the CIWA-Ar tool and documented the patient's score. Patients received diazepam 10 mg or lorazepam 2 mg orally when CIWA-Ar scores demonstrated that patients were exhibiting mild withdrawal (CIWA-Ar score 10 to 20). Doses were doubled when scores exceeded 20. The primary investigator (See) and a medical resident collected the study data. The study methods and design were approved by the hospital's Institutional Review Board. The clinical pharmacist educated the nursing staff and clinicians on the rationale and details of how to implement the CIWA-Ar protocol via designated training sessions, teaching afternoons, and constant reinforcement and encouragement while on the medical floor.

Statistical Analysis

Data were analyzed with *Stata Statistical Software: Release 8* (College Station, TX: StataCorp LP) using chi-square, Fisher exact, and *t* tests where appropriate.

RESULTS

A total of 46 patients qualified for inclusion in this pilot study. The baseline characteristics between groups were similar, with a majority of patients having a history of alcohol abuse or dependence (80%) (see Table 1). Of the 21 patients in the benzodiazepine group, 2 patients received lorazepam, while the rest received diazepam. Patients in the phenobarbital group received a mean dose of 663 mg (standard deviation [SD] 834 mg), while patients in the benzodiazepine group received a mean dose of diazepam 14 mg (SD 36 mg) and lorazepam 0.86 mg (SD 2.72 mg). Importantly, 62% of patients on the benzodiazepine symptom-triggered protocol did not require any drug, whereas 100% of patients in the phenobarbital group received a drug ($P < 0.001$). This means that if these patients had received the previous hospital standard of fixed-dose phenobarbital, they would all have received at least 5 days of drug whether or not they had symptoms. The length of stay was similar in both groups. The phenobarbital group trended toward being on the protocol longer than the benzodiazepine group (3.12 vs 2.57 days; $P = 0.25$). Additionally, 36% of patients in the

Table 1. Baseline Demographics

Demographics	*Phenobarbital (n = 25)*	*Benzodiazepine (n = 21)*
Male	92% (23)	90% (19)
Age (years) (mean)	47 (range, 36 to 63)	51 (range, 26 to 78)
Race		
Caucasian	16 % (4)	24% (5)
African American	40 % (10)	24% (5)
Other	28% (7)	24% (5)
Unknown	16% (4)	29% (6)
Detoxification history	68% (17)	43% (9)
History of alcohol withdrawal symptoms	72% (18)	29% (6)
History of alcoholic seizures	60% (15)	33% (7)
Daily alcohol intake (drinks)	17 (4 to 40)	21 (6 to 40)
Intoxicated on admission	20% (5)	29% (6)
Hours since last drink (mean)	23 (range, 0 to 96)	36 (range, 4 to 168)

phenobarbital fixed-dose group left the hospital against medical advice (AMA), while only 9.5% of patients in the benzodiazepine group left AMA (P = 0.045). No patient experienced any adverse events in the benzodiazepine group, while 7 of 12 patients in the phenobarbital group had adverse events (P < 0.001). These included 1 case each of hyponatremia, arrhythmia, chest pain, diabetic ketoacidosis, severe detoxification symptoms, nausea and vomiting, and nonsustained ventricular tachycardia that required transfer to the coronary care unit.

DISCUSSION

The pilot study demonstrated that symptom-triggered therapy using benzodiazepines resulted in better outcomes than those patients on fixed-dose phenobarbital. The most significant finding in the pilot was that almost two-thirds of patients in the symptom-triggered group did not require any drug. Avoiding unneeded sedatives may render the patient more able to participate in other necessary treatments. Additionally, patients in this group left against medical advice less often than those in the fixed-dose phenobarbital group. While not statistically significant, there was a trend toward decreased length of stay and days on protocol in the symptom-triggered benzodiazepine group.

Limitations of this study include a small sample size and a retrospective design using a historical control. Incomplete data were found in the charts, which could have affected the statistical analysis. In addition, there were some cases in which the CIWA-Ar protocol was incorrectly used. Specifically, in some patients, the protocol was continued despite the fact that the protocol could have been stopped because the patient was no longer at risk of AWS. This meant that nurses continued to assess the patients and presumably, the scores were not high enough to require any drug. It was also noted that occasionally the incorrect dose was given according to the score. Both of these types of misuse could be attributed to user error. In 1 case, a patient feigned symptoms to increase his CIWA-Ar score and thus was given medication.

As with any new protocol, various questions were raised during the pilot study. First, clinicians inquired about what to do if the patient presented with a positive blood alcohol level. Patients with chronic alcohol dependence can still go into alcohol withdrawal despite the presence of alcohol in the blood. An acute decline in their blood alcohol content can precipitate withdrawal.[12] It was recommended to order the symptom-triggered protocol as per usual procedure. The second question was what to do with a patient who was on clonazepam at home for anxiety. Due to the concern of benzodiazepine withdrawal, clonazepam was continued and the benzodiazepine-symptom triggered protocol was used as usual to prevent alcohol withdrawal symptoms.

The phenobarbital patients were sicker at baseline as defined by the presence of detoxification history, history of alcohol withdrawal symptoms, and seizures. Inadequate treatment for alcohol withdrawal symptoms may have contributed to the large number of patients who left AMA. In addition, patients may have received phenobarbital in the emergency department before arriving on the family medicine floor. This may have skewed the results of the study.

One of the major concerns with implementing this type of protocol is the ability of nurses to carry out the protocol. The CIWA-Ar assessment tool requires that nurses go through the 10 assessment questions to determine a patient's CIWA-Ar score. This nurse-driven protocol requires that all nurses are educated on the rationale and method of activating this protocol. The clinical pharmacist in-serviced all of the nurses on the family medicine inpatient ser-

vice. Each nurse was given a handout that included the rationale for using symptom-triggered protocols and benzodiazepines and an example of how to use the protocol. Prior to the pilot study, nurses expressed concern that this assessment would be too time-intensive. Nurses should be able to conduct the CIWA-Ar assessment in less than 2 minutes.[10] This was confirmed during the pilot. Nurses were reminded that they were already doing this assessment, except that now it had to be documented to determine a score. In addition, nurses were reassured that this assessment tool was validated, reproducible, and reliable.[10] It was found that once the nurses understood the rationale behind the protocol, they were able to implement the protocol with minimal problems.

The nurses were also unfamiliar and initially uncomfortable with giving diazepam 10 mg until the pharmacist explained the rationale behind using this particular dose and medication. The goal of treating alcohol withdrawal is to sedate the patient while ensuring normal vital signs.[2] Diazepam is a rapid-acting benzodiazepine that has an active metabolite with a long half-life ensuring a smooth taper as the alcohol levels decrease during the patient's stay. This "autotitration" allows the clinician to administer 1 dose of diazepam and the drug levels will decline as the symptoms of AWS resolve.[2]

In addition to the nursing staff, the role of the pharmacist was crucial to implementing this protocol. Educating and reassuring the other clinicians (physicians and nurses) on the safety and effectiveness of benzodiazepines, and the limitations and risks of continued phenobarbital use was very important in overcoming their reluctance and changing their practice patterns.

CONCLUSION

This pilot study demonstrated that a symptom-triggered alcohol withdrawal protocol using benzodiazepines could be successfully implemented on an inpatient adult medicine service operated by family physicians. The data revealed a trend toward less medication use, decrease in duration of treatment and length of stay, and a significant difference in adverse events compared with patients on fixed-dose phenobarbital. The most notable result of this study is that over two-thirds of patients in the symptom-triggered benzodiazepine group required no drug. Based upon this study, the fixed-dose protocol at our institution was replaced system-wide with the CIWA-Ar protocol, and became fully implemented in the hospital computerized physician order entry system.

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Appendix A. The Clinical Institute Withdrawal Assessment for Alcohol, Revised (CIWA-AR)[8]

Appendix: Addiction Research Foundation Clinical Institute Withdrawal Assessment for Alcohol (CIWA-Ar)

Patient_____ **Date** |__|__|__| y m d **Time**____:____ **(24 hour clock, midnight=00:00)**

Pulse or heart rate, taken for one minute: _____ **Blood pressure:** _____/_____

NAUSEA AND VOMITING—As "Do you feel sick to your stomach? Have you vomited?" Observation.
0 no nausea and no vomiting
1 mild nausea with no vomiting
2
3
4 intermittent nausea with dry heaves
5
6
7 constant nausea, frequent dry heaves and vomiting

TREMOR—Arms extended and fingers spread apart. Observation.
0 no tremor
1 not visible, but can be felt fingertip to fingertip
2
3
4 moderate, with patient's arms extended
5
6
7 severe, even with arms not extended

PAROXYSMAL SWEATS—Observation.
0 no sweat visible
1 barely perceptible sweating, palms moist
2
3
4 beads of sweat obvious on forehead
5
6
7 drenching sweats

ANXIETY—Ask "Do you feel nervous?" Observation.
0 no anxiety, at ease
1 mildly anxious
2
3
4 moderately anxious, or guarded, so anxiety is inferred
5
6
7 equivalent to acute panic states as seen in severe delirium or acute schizophrenic reactions

AGITATION—Observation.
0 normal activity
1 somewhat more than normal activity
2
3
4 moderately fidgety and restless
5
6
7 paces back and forth during most of the interview, or constantly thrashes about

TACTILE DISTURBANCES—Ask "Have you any itching, pins and needles sensations, any burning, any numbness or do you feel bugs crawling on or under your skin?" Observation.
0 none
1 very mild itching, pins and needles, burning or numbness
2 mild itching, pins and needles, burning or numbness
3 moderate itching, pins and needles, burning or numbness
4 moderately severe hallucinations
5 severe hallucinations
6 extremely severe hallucinations
7 continuous hallucinations

AUDITORY DISTURBANCES—Ask "Are you more aware of sounds around you? Are they harsh? Do they frighten you? Are you hearing anything that is disturbing to you? Are you hearing things you know are not there?" Observation.
0 not present
1 very mild harshness or ability to frighten
2 mild harshness or ability to frighten
3 moderate harshness or ability to frighten
4 moderately severe hallucinations
5 severe hallucinations
6 extremely severe hallucinations
7 continuous hallucinations

VISUAL DISTURBANCES—Ask "Does the light appear to be too bright? Is its colour different? Does it hurt your eyes? Are you seeing anything that is disturbing to you? Are you seeing things you know are not there?" Observation.
0 not present
1 very mild sensitivity
2 mild sensitivity
3 moderate sensitivity
4 moderately severe hallucinations
5 severe hallucinations
6 extremely severe hallucinations
7 continuous hallucinations

HEADACHE, FULLNESS IN HEAD—Ask "Does your head feel different? Does it feel like there is a band around your head?" Do not rate for dizziness or lightheadedness. Otherwise, rate severity.
0 not present
1 very mild
2 mild
3 moderate
4 moderately severe
5 severe
6 very severe
7 extremely severe

ORIENTATION AND CLOUDING OF SENSORIUM—Ask "What day is this? Where are you? Who am I?"
0 oriented and can do serial additions
1 cannot do serial additions or is uncertain about date
2 disoriented for date by no more than 2 calendar days
3 disoriented for date by more than 2 calendar days
4 disoriented for place and/or person

Total CIWA-A Score_____
Rater's Initials_____
Maximum Possible Score 67

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Appendix B. Order Sheet

DATE	TIME	ORDERS		
		Allergies:		
		MEDICATION ADMINISTRATION PROTOCOL: Detoxification Medicines – Hold dose if patient is deeply sedated.		
		CIWA Score		
		1-9 ☐ **Give NO Medicine** Repeat CIWA in 4 hours ☐ Discontinue protocol when CIWA score is less than 10 x 24 hours		
			Choose Protocol	
			☐ ***Diazepam Protocol**	☐ ****Lorazepam Protocol**	☐ **IM Protocol (If Patient Cannot Tolerate PO)**
		10-20	Diazepam 10mg PO every hour PRN Repeat CIWA every hour	Lorazepam 2mg PO every hour PRN Repeat CIWA every hour	Lorazepam 2mg IM every hour PRN Repeat CIWA every hour
		Greater than or equal to 21	Diazepam 20mg PO every hour PRN Repeat CIWA every hour	Lorazepam 4mg PO every hour PRN Repeat CIWA every hour	Lorazepam 4mg IM every hour PRN Repeat CIWA every hour
		NOTE: PRN doses depend on CIWA Score		
		*Preferred choice in most patients **Preferred choice for patients with significant liver disease (AST or ALT greater than 400 U/L), severe respiratory disease, pregnancy, head injury ***If patient requires 3 or more every hour doses of medication, contact MD.		
		MEDICATIONS:		
		☐ Thiamine 100mg po daily for 5 days ☐ Multivitamin 1 tab po daily ☐ Folic Acid 1mg po daily ☐ Acetaminophen 325mg po every 6 hours prn headache or muscle pain ☐ Maalox 30mL po every 4 hours prn indigestion		
		☐ **Discontinue all alcohol detoxification orders if patient is transferred off 9 Iinsky and contact MD**		
		MD signature: _____ Beeper #: _____		
		Date: _____ Time: _____		